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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,029	11/17/2003	Martin Nicklin	24299-524CON	5844

7590 06/14/2006

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,029	NICKLIN ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8 , drawn to methods for determining whether a subject has a disease by assaying for an IL-1 allele, classified in Class 435, subclass 6.

II. Claims 9-17, drawn to methods for determining whether a subject has a disease by assaying for a characteristic pattern of an IL-1 haplotype, classified in Class 435, subclass 6.

III. Claims 18-26, drawn to IL-1 polynucleotides and kits comprising IL-1 polynucleotides, classified in Class 536, subclass 23.5.

IV. Claims 27-39, drawn to methods for selecting a therapy for an individual by assaying for an IL-1 haplotype and selecting a therapy that compensates for the IL-1 haplotype, classified in Class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are drawn to patentably distinct methods, each requiring the use of different reagents and having different outcomes. The claims of invention I are drawn to methods for detecting an allele, while the claims of invention II are drawn to methods for detecting a haplotype. The chemical and structural features of each of the individual alleles is distinct form the chemical and structural features of the individual haplotypes. Further, the functional properties associated with the individual alleles is distinct from that associated with each of the combination of alleles, each allele and combination of alleles having a different biological activity and effect.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the nucleic acids of invention III can be used in a materially different process, such as for synthesizing nucleic acids or proteins or in screening methods for determining the effect of an agent on gene expression.

Inventions I and IV are drawn to patentably distinct methods, each requiring the use of different reagents, having different method steps and different effects. The method of invention I requires the use of probes and primers to detect a nucleic acid and has the objective of determining an individual's predisposition to a disease. Invention IV requires the use of a therapeutic compound and involves treating a subject with a therapeutic compound, ascertaining whether a phenotype is alleviated by the treatment and determining if a compound compensates for a haplotype and administering a therapeutic compound to a subject.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the nucleic acids of invention III can be used in a materially different process, such as for

synthesizing nucleic acids or proteins or in screening methods for determining the effect of an agent on gene expression.

Inventions II and IV are drawn to patentably distinct methods, each requiring the use of different reagents, having different method steps and different effects. The method of invention I requires the use of probes and primers to detect a nucleic acid and has the objective of determining an individual's predisposition to a disease. Invention IV requires the use of a therapeutic compound and involves treating a subject with a therapeutic compound, ascertaining whether a phenotype is alleviated by the treatment and determining if a compound compensates for a haplotype and administering a therapeutic compound to a subject.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the nucleic acids of invention III can be used in a materially different process, such as for synthesizing nucleic acids or proteins or in general methods for detecting IL-1 nucleic acids.

Allele and Haplotype Election Requirement Applicable to Invention I-IV

4. In addition, inventions I-IV read on patentably distinct inventions drawn to multiple alleles and haplotypes. The claims encompass polynucleotides having different nucleotide sequences, each containing a different polymorphism and methods for

detecting each of the distinct polynucleotides and combinations thereof. The chemical structure of each polymorphism and of each polynucleotide containing the polymorphism is distinct from each of the other polymorphisms and polynucleotides. For example, a polynucleotide comprising the polymorphism at position 89 of IL-1RN is chemically, structurally and functionally distinct from a polynucleotide comprising the polymorphism at position 49 of IL-1F5. Each of the polynucleotides binds to a different nucleotide sequence, has a different melting temperature, a different specificity of hybridization and a different biological effect. Additionally, each combination of polymorphisms is distinct from one another, since the particular combinations of polymorphisms (haplotypes) each have a different effect and possess their own functional activity.

It is noted that each of the polymorphic variants constitutes a distinct chemical compound and each has a distinct functional property. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each polymorphism and each haplotype is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

In response to this Office action, Applicant is required to elect one particular polymorphism or one particular combination of polymorphisms selected from the group of diverse polymorphisms set forth in Figures 1, 2A, 2B, 3A, 3b, 4B, 5A, 5B, 6A, 6B, 7A and 7B.

4. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their divergent subject matter. Further, these inventions require different database searches that are not co-extensive. For example, a search for polynucleotides comprising position 89 of IL-1RN would not be co-extensive with a search for polynucleotides comprising the polymorphism at position 49 of IL-1F5. Further, a reference which anticipates or renders obvious polynucleotides comprising position 89 of IL-1RN would not also necessarily anticipate or render obvious polynucleotides comprising the polymorphism at position 49 of IL-1F5. Similarly a finding that polynucleotides comprising position 89 of IL-1RN are novel and unobvious over the prior art would not necessarily extend to a holding polynucleotides comprising the polymorphism at position 49 of IL-1F5 are also novel and unobvious over the prior art.

Further, each of the combinations of polymorphisms is distinct from the individual polymorphisms because the combinations of polymorphisms have distinct structural and functional properties, such that the combined haplotypes have distinct effects from one another. Additionally, a reference which renders obvious a single polymorphism will not necessarily also render obvious a combination of these polymorphisms. Similarly, a search indicating that a particular combination of alleles is novel or unobvious would not extend to a holding that a single polymorphisms or a different combination of polymorphisms is also unobvious.

Accordingly, examination of these distinct inventions would pose a serious burden on the Office and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
June 12, 2006

CARLA J. MYERS
PRIMARY EXAMINER